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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,533	12/29/2000	Stephen M. Coutts	252312005704	1380

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EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/24/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/752,533

Applicant(s)

Coutts

Examiner

David Lukton

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 4, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-45 is/are pending in the application.
- 4a) Of the above, claim(s) 32, 44, and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-31 and 33-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Pursuant to the directives of paper No. 16 (filed 10/4/02), claim 1 has been amended.

Claims 22-45 remain pending.

Applicants' election of Group 3 is acknowledged, (at least one of the molecules falls within the scope of G6), as is the elected specie (compound 3-II), figure 6A.

Claims 44-45 are withdrawn from consideration in accordance with the election. In addition, claim 32 is withdrawn from consideration; in the specie, the "biologically active molecule" is a polynucleotide, which is not encompassed by claim 32. Claims 22-31, 33-43 are examined in this Office action.

✱

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is asserted in claim 36 that "antibody-mediated" pathologies can be successfully treated. However, most human diseases thus far documented are in some form or other,

"antibody-mediated". Such diseases would include, for example, cancer, diabetes, Alzheimer's Disease, inflammation, and arthritis. It may be the case that applicants have shown that some suppression of antibody formation can be achieved when melittin is conjugated to a valency platform (example 11, pages 116-123). However, it does not follow therefrom that these, or any other human diseases can be successfully treated.

If, for example, a person who is afflicted with SLE (lupus) is producing antibodies at the rate of 100 "units" per day in the absence of the conjugate, and 90 units per day in the presence of the conjugate, one could say the antibody production had been suppressed. But this does not mean that the illness will not worsen. Moreover, adverse immune reactions are not limited to the consequences of excess antibody production alone. In addition to the foregoing, claim 36 would also encompass diseases in which the immune response is insufficient (as opposed to the situation in an autoimmune disorder). In such cases, suppressing antibody production further will only exacerbate the patient's condition.

Accordingly, enablement is lacking for the invention of claim 36.

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The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time

the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 22-25, 33, 35-37, 44 are rejected under 35 U.S.C. §103 as being unpatentable over Greenfield (U.S.P. 4,933,288) or Woo (U.S.P. 5,130,116) or Ferris (USP 4,808,705) or Sivam (USP 4,981,979).

Each of Greenfield, Woo, Ferris and Sivam teaches immunoconjugates. Formula 2, which is encompassed by claim 22, would appear to encompass immunoconjugates. Claim 22 requires "branching groups", but this requirement is met by the lysines and cysteines of the immunoglobulin which react with the therapeutic agent. In addition, it is noted that claim 22 requires that there be two or more different conjugates. One of ordinary skill, however, would have expected a multiplicity of products in forming a conjugate. First, antibodies are glycoproteins, and as such, there is some diversity in the carbohydrate portion. In addition, if polyclonal antibodies are used, there would be multiple protein sequences to begin with. Finally, the reality of conjugate chemistry (with macromolecules) is that a distribution of stoichiometries is generally obtained. If

a given protein has e.g., 10 available lysines, and a stoichiometric excess of (activated) "therapeutic agent" is added, one would expect to obtain a distribution of stoichiometries, e.g., a few compounds exhibiting a 4:1 stoichiometry, a few more exhibiting a 5:1 stoichiometry, etc. Thus, in general, it would be far more difficult to produce just one immunoconjugate, than to produce several simultaneously.

Thus, the claims are rendered obvious.

✱

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800